K132478

APR 1 1 2014

APPENDIX F

510(k) Summary for AIR-FLOW handy 3.0

AIR-FLOW handy 3.0
Special 510(k) Premarket Notification
510(k) Summary
(per 21 CFR 807.92(c))

1. SPONSOR/MANUFACTURER

E.M.S. ELECTRO MEDICAL SYSTEMS S.A.
Ch. de la Vuarpillière 31
CH - 1260 Nyon
Switzerland

Contact Person: Suzanne Fassio-Hardy
Telephone: +41 (0)22 994 47 00

Date Prepared: August 7, 2013

2. DEVICE NAME:

Proprietary Name:	AIR-FLOW handy 3.0
Common/Usual Name:	Dental handpiece
Classification Name:	Dental handpiece and accessories

3. PREDICATE DEVICES

- E.M.S. ELECTRO MEDICAL SYSTEMS S.A.,AIR-FLOW handy 2 (K022119)
- E.M.S. ELECTRO MEDICAL SYSTEMS S.A., AIR-FLOW MASTER (K073284)
- E.M.S. ELECTRO MEDICAL SYSTEMS S.A., AIR-FLOW MASTER PIEZON (K110173)

4. DEVICE DESCRIPTION

The proposed AIR-FLOW handy 3.0 is a modification of the AIR-FLOW handy 2 Dental Handpiece previously cleared under K022119. This device modification has been submitted as a Special 510(k) Premarket Notification because the indications for use for the proposed AIR-FLOW handy 3.0 are identical to the parent AIR-FLOW handy 2. The fundamental technology and design of the proposed AIR-FLOW handy 3.0 are essentially identical to the AIR-FLOW handy 2 dental handpiece.

Both the proposed AIR-FLOW handy 3.0 and the predicate AIR-FLOW handy 2 connect to a standard turbine connection on a dental operative unit and deliver a mixture of water, air, and dental powder to a treatment site.

Modifications made to the AIR-FLOW handy 2 Dental Handpiece to produce the AIR-FLOW handy 3.0 were limited to minor design changes to enhance the ergonomics of the design, including:

- Location of the powder chamber is modified to improve the visibility of the mouth of patient by the practitioner during the treatment.
- Slimmer shape of the powder chamber to be in-line with the body of the device to improve the visibility of the mouth of patient by the practitioner during the treatment.
- Diameter of the powder chamber cap is reduced to be in-line with new design of the powder chamber.
- The powder chamber capacity has been slightly decreased to 21g from 23g to fit new ergonomic design.
- The body of the handy 3.0 is made of 2 glued molded part instead of 1 molded part
- The handpiece is shorter and slimmer to improve ergonomics.

Accessories were included to aid in filling the powder chamber and removing residual powder from the handpiece channels.

In addition, the AIR-FLOW CLASSIC COMFORT prophylaxis powder has been added to the panel of available prophylaxis powders. The chemical composition of the AIR-FLOW CLASSIC COMFORT Powder is identical to the AIR-FLOW CLASSIC that was described in the 510(k) Premarket Notification for the AIR-FLOW MASTER (K073284). The grain size was slightly reduced from a median particle size of < 65µm for the AIR-FLOW CLASSIC to <40 µm for the AIR-FLOW CLASSIC COMFORT prophylaxis powder to improve patient comfort during the prophylaxis treatment.

5. INTENDED USE

The AIR-FLOW handy 3.0 is a dental handpiece intended for use in the cleaning and polishing of teeth by the projection of a mixture of water, air, and prophylaxis powder onto the tooth surface. The device removes soft deposits and areas of discoloration and can be used to prepare teeth for dental procedures such as the placement of composite fillings, porcelain inlays, and laminate veneers. The device can be used to clean implant abutments and to clean teeth prior to treatments such as shade matching, fluoridation, and bleaching. The device can also be used to degrease crowns and bridges prior to placement and clean fixed bands and brackets on orthodontic appliances.

6. SUMMARY OF TECHNOLOGICAL CHARACTERISTICS COMPARED TO THE PREDICATE DEVICE

The proposed AIR-FLOW handy 3.0 is similar in design and materials to the AIR-FLOW handy 2 Dental Handpiece. Both the proposed AIR-FLOW handy 3.0 and the predicate AIR-FLOW handy 2 connect to a standard turbine connection on a dental operative unit and consist of a hand-held device containing air and water lines, powder chamber with cap and an AIR-FLOW nozzle. The proposed and predicate handpieces deliver a mixture of water, air, and dental powder to a treatment site. Differences between the proposed and predicate handpieces were limited to design changes to improve the ergonomics of the handpiece design and ease of use. The proposed AIR-FLOW CLASSIC COMFORT prophylaxis powder was produced with a smaller grain size to improve patient comfort.

7. SUMMARY OF NON-CLINICAL PERFORMANCE TESTING AS BASIS FOR SUBSTANTIAL EQUIVALENCE

Non-clinical performance testing demonstrates that the AIR-FLOW handy 3.0 fulfills the prospectively defined performance specifications. The similarities in intended use, operational characteristics, and functional technological characteristics between the AIR-FLOW handy 3.0 and the AIR-FLOW handy 2 lead to a conclusion of substantial equivalence between the proposed and predicate devices.

8. SUMMARY OF CLINICAL TESTING AS BASIS FOR SUBSTANTIAL EQUIVALENCE

Clinical testing was not conducted.

9. CONCLUSIONS DRAWN FROM NON-CLINICAL AND CLINICAL TESTING

The similarities in intended use, operational characteristics, and functional technological characteristics between the AIR-FLOW handy 3.0 and the AIR-FLOW handy 2 lead to a conclusion of substantial equivalence between the proposed and predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

April 11, 2014

E.M.S. Electro Medical Systems S.A.
% Cynthia Nolte
Dir., Med. Dev. Reg. Svces.
AptivSolutions
62 Forest St., Ste 300
Marlborough, MA 01752 US

Re: K132478
Trade/Device Name: Air-flow handy 3.0
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece
Regulatory Class: Class I
Product Code: EFB
Dated: February 11, 2014
Received: February 12, 2014

Dear Dr. Cynthia Nolte:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mary S. Runner -S FDA

Erin I. Keith, M.S.
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K132478

Device Name: AIR-FLOW handy 3.0

Indications for Use:

The AIR-FLOW handy 3.0 Dental Handpiece is a dental handpiece intended for use in the cleaning and polishing of teeth by the projection of a mixture of water, air, and EMS prophylaxis powder onto the tooth surface. The device removes soft deposits and areas of discoloration and can be used to prepare teeth for dental procedures such as the placement of composite fillings, porcelain inlays, and laminate veneers. The device can be used to clean implant abutments and to clean teeth prior to treatments such as shade matching, fluoridation, and bleaching. The device can also be used to degrease crowns and bridges prior to placement and clean fixed bands and brackets on orthodontic appliances.

Prescription Use _X_ AND/OR Over-The-Counter Use ___
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Sheena A. Green -S
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